UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,876	11/28/2006	Daniel Tod Smithey	0003.0551/PC32026A	1776

152 7590 07/15/2011

CHERNOFF, VILHAUER, MCCLUNG & STENZEL, LLP
601 SW Second Avenue
Suite 1600
PORTLAND, OR 97204-3157

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1613	

MAIL DATE	DELIVERY MODE
07/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/596,876
Filing Date: November 28, 2006
Appellant(s): SMITHEY ET AL.

Dennis E. Stenzel
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 04/25/2011 appealing from the Office action mailed 01/04/2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 45, 46 and 49-62 are pending.

Claims 49-52 are withdrawn from consideration.

Claims 45, 46 and 53-62 are rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

The rejection of claims 55 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment filed after the final rejection as stated in the advisory action of 02/15/2011.

The rejection of claims 45, 46, 54 and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Infeld et al. (WO 02/089835) in view of Beyerinck et al. (US 6,763,607) is withdrawn.

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

20010053778 A1	HOOVER et al	12-2001
20010053791 A1	BABCOCK et al	12-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 53 was inadvertently omitted in paragraph 19 of the office action of 01/04/2011. Babcock specifically notes in paragraph [0060] that amorphous state is represented by solid solution in which the drug is homogeneously distributed.

Claims 45, 46 and 53-62 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hoover et al. (US 20010053778 A1) and Babcock et al. (US 20010053791 A1).

Hoover is directed to pharmaceutical composition comprising glycogen phosphorylase (GPI), a sparingly soluble drug, in the form of amorphous solid dispersions and which is a simple physical mixture of the GPI and concentration enhancing polymer; the physical mixture in the case of oral administration constitutes layers where one or more of the layers comprise the amorphous GPI and one or more of the layers comprise the concentration enhancing polymer; Hoover also teaches that the GPI and the concentration enhancing polymer may be present in different dosage forms (see paragraph [0193]); one of the goals of Hoover is to provide a composition comprising GPI and concentration enhancing polymer that improves the bioavailability of the GPI (see the whole document with emphasis on paragraphs [0011]-[0018], [0026], [0193]).

The composition of Hoover comprises various additives and excipients to promote the chemical and physical stability of the GPI (see paragraph [0207]). The composition of Hoover contains diluents such as lactose, mannitol, xylitol, microcrystalline cellulose, calcium diphosphate, and starch (paragraph [0200]). The dosage form of Hoover does not use poloxamer.

Babcock is also directed to physical mixture of glycogen phosphorylase inhibitor (GPI), concentration enhancing polymer, diluents such as lactose, mannitol, xylitol, dextrose, sucrose, sorbitol, compressible sugar, microcrystalline cellulose, powdered cellulose, starch, pregelatinized starch, dextrates, dextran, dextrin, dextrose, maltodextrin, calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, magnesium carbonate, magnesium oxide, poloxamers, polyethylene oxide, and hydroxypropyl methyl cellulose (paragraph [0126]); Babcock also teaches that the dosage form can be stabilized with additives such as various grades of polysorbate surfactant (paragraph [0142]) (see the whole document with emphasis on the title, paragraphs [0019], [0060], [0062], [0250], [0253]).

Thus, taking the teachings from Hoover and Babcock, one having ordinary skill in the art at the time the invention was made would be motivated to formulate GPI as layered tablet dosage form that contains concentration enhancing polymer, polysorbate for stabilizing the GPI, and diluents such as lactose, mannitol, xylitol, dextrose, sucrose, sorbitol, compressible sugar, microcrystalline cellulose, powdered cellulose, starch, pregelatinized starch, dextrates, dextran, dextrin, dextrose, maltodextrin, calcium carbonate, dibasic calcium phosphate, tribasic calcium phosphate, calcium sulfate, magnesium carbonate, magnesium oxide, poloxamers, polyethylene oxide, and hydroxypropyl methyl cellulose with the expectation that the bioavailability of the

GPI is improved as anticipated by Hoover and Babcock. In the alternate, because Babcock lists poloxamers, lactose, mannitol, xylitol, microcrystalline cellulose, calcium diphosphate, and starch as diluents, which are also the diluents listed by Hoover except for poloxamer, it flows any of these customary diluents can be used with the GPI composition.

When the physical mixture in the case of oral administration constitutes layers where one or more of the layers comprise the amorphous GPI and one or more of the layers comprise the concentration enhancing polymer the limitations of claims 54-56 are met and 53 since amorphous is a state in which the drug is homogeneously distributed as a solid solution. The drug composition comprising GPI, concentration enhancing polymer and poloxamer meets claims 45 and 46 since the GPI is amorphous and neither Hoover nor Babcock teaches molecular dispersion. Claims 58-62 recite the characteristic of the dosage form and thus, the modified dosage form of Hoover and Babcock meets the claims. The dosage form when administered would also have the physical mixture of GPI and concentration enhancing polymer and poloxamer in the same environment of use after administration.

(10) Response to Argument

Argument: Appellant argues that the rational to pick one excipient from a list of excipients containing 107 and expect GPI's bioavailability to be improved as reasoned by the examiner in the last two lines of paragraph 23 of the Final Rejection of 01/04/2011 is not supported by the disclosure in Babcock at paragraph [0125] since "customary formulation excipients" that "may be used for customary purposes and in typical amounts without adversely affecting the properties of the compositions," would not harm "the beneficial properties (such as bioavailability) of his GPI compositions so long as they are used in conventional ways known in

the pharmaceutical arts" and that this does not amount to a teaching or suggestion that inclusion of such excipient will improve the bioavailability argued by the examiner.

Response: Both Hoover (paragraph [0010]) and Babcock (paragraph [0004]) desire to enhance aqueous concentration and bioavailability of GPI. Appellant presents and the examiner agrees that customary excipients listed in paragraphs [0126]-[0132] of Babcock do not harm beneficial properties, including bioavailability, of the GPI composition. Hoover uses the diluents such as lactose, mannitol, xylitol, microcrystalline cellulose, calcium diphosphate, and starch (paragraph [0200]) with GPI. The examiner did not pick one excipient from a list of 107. Rather, Babcock lists poloxamer as one of 26 diluents and fillers (paragraph [0126]) that are useable with the GPI and ones that would not adversely affect the properties of the composition. Therefore, Babcock has recognized poloxamer as being equivalent to or interchangeable with the same customary diluents disclosed for use with GPI in Hoover. A person of ordinary skill in the art would have recognized the interchangeability of the "customary" diluents, poloxamer, lactose, mannitol, xylitol, microcrystalline cellulose, calcium diphosphate, and starch with the expectation that poloxamer or any of the other interchangeable diluents would not adversely harm the GPI composition as taught by Babcock and as recognized by appellant. Therefore, interchanging poloxamer for any of the other diluents in Hoover does not play substantially different role other than diluent. The goal and expectation would be sustained enhancement of aqueous concentration and bioavailability of GPI.

Response to Appellant's Remarks on claim 53: Claim 53 was inadvertently omitted. As may be noted, Babcock notes in paragraph [0060], which was referenced in the last line of paragraph 22 of the office action of 01/04/2011. In that paragraph, Babcock discloses that

amorphous state is represented by solid solution in which the drug is homogeneously distributed. Paragraph [0027] of Hoover also discloses that GPI is homogeneously distributed throughout the polymer and paragraph [0184] thinks of the GPI as a solid solution.

Therefore, Hoover in view of Babcock has been properly shown to render obvious claim 45 and the claims dependent therefrom. The rejection should be maintained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613

Conferees:

Brian-Yong S. Kwon
SPE, Art Unit 1613

Fereydoun G. Sajjadi
SPE, Art Unit 1617

/Brian-Yong S Kwon/
Supervisory Patent Examiner, Art Unit 1613

/Fereydoun G Sajjadi/
Supervisory Patent Examiner, Art Unit 1617